REMARKS

Claims 1, 2, and 6-10 are pending. Claims 3 and 4 are canceled. Claims 6-10 are withdrawn from consideration. Reconsideration is respectfully requested in view of the following remarks.

I. Claim Rejections – 35 USC § 102(b)

The Examiner has rejected claims 1 and 2 under 35 U.S.C. §102(b) as being anticipated by Randall et al. (1993) *Vaccine* 12:1247-1252.

Independent claim 1 as amended specifies a monoclonal antibody that specifically binds to a histidine portion of a fusion polypeptide, but not to the non-histidine portion of the fusion polypeptide. The histidine portion of the fusion polypeptide comprises 6-18 successive histidine residues. Support for the amended claim language appears in the specification, for example, at page 6, lines 17-18.

Randall et al. fails to disclose such a claimed monoclonal antibody. In contrast, Randall focuses on developing vaccines against various recombinant antigens. The tag sequences, a 12-amino-acid-N-terminal His tag (His) and a C-terminal tag (Pk), were merely used as tags for purification of the recombinant proteins for immunization purposes. *See* Abstract. Nowhere could be found a teaching that a monoclonal antibody was developed against the His tag. Instead, Randall et al. discloses mouse sera which cross-reacted with not only the antigen, but also with both the N- and C-terminal tags. Page 1253, first paragraph. Thus, the cited reference fails to teach the claimed monoclonal antibody that specifically binds to a histidine portion of a fusion polypeptide, but not to the non-histidine portion of the fusion polypeptide. Therefore, Randall et al. fails to anticipate the claimed invention under 35 U.S.C. §102(b). Withdrawal of these grounds of rejection is respectfully requested.

II. Claim Rejections - 35 USC 103(a)

The Examiner has also rejected Claims 1 and 3 as being unpatentable over Randall et al. in view of Harlow et al. (1988) *Antibodie: A Laboratory Manua*l, pages 139-147).

To establish a prima facie case of obviousness, the Examiner bears the burden of proving 1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; 2) the prior art contains a suggestion or motivation to combine the prior art references in such a way as to achieve the claimed invention; and 3) one of ordinary skill in the art at the time the invention was made would have reasonable expectation of success of the claimed invention. *In re Vaeck*, 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *In re O'Farrell*, 853 F. 2d 894, 903-904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); and *In re Dow Chem.*, 837 F. 2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

As discussed in detail above, Randall et al. fails to teach or suggest the claimed monoclonal antibody that specifically binds to a histidine portion of a fusion polypeptide, but not to the non-histidine portion of the fusion polypeptide. On the other hand, Harlow et al. is a general laboratory manual for generation of monoclonal antibodies. Nowhere does Harlow et al. teach or suggest the claimed antibody specifically against the histidine portion of a fusion polypeptide. Thus, Harlow et al. fails to fill in the gap between the teaching of Randall et al. and the claimed invention. Thus, the cited references combined do not teach or suggest all the claim limitations. In fact, Randall et al. considered polyclonal antibodies that cross-react with the His tag undesirable, thus discouraging one of ordinary skill in the art to develop monoclonal antibody that only binds to the His tag.

In view of the failure of the cited references to teach or suggest the claimed invention, Applicants submit that a prima facie case of obviousness has not been established. Withdrawal of the rejection under 35 U.S.C §103(a) is therefore respectfully requested.

III. Claim Rejections –Nonstatutory Obviousness-Type Double Patenting

Claims 1-3 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,790,940.

Applicant respectfully disagrees with the Examiner's grounds for rejection. Yet, solely in an effort to further prosecution, and without prejudice, Applicant herein submits a Terminal Disclaimer for any term extending beyond the term of U.S. patent No. 6,790,940. This submission is made to put the pending claims in condition for allowance. In filing the Disclaimer, Applicant specifically

reserves the right to address any double patenting issues in the future, whether or not mentioned in this Response, should the need arise. Applicant makes particular note of MPEP 804.02 II and established case law findings of the Federal Circuit, in *Quad Environmental Technologies v. Union Sanitary District,* 946, F. 2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), that the filing of a Terminal Disclaimer to obviate a rejection based on a non-statutory double patenting is not an admission of the propriety of the rejection. The filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection.

IV. Double Patenting Under 35 USC §101

Claim 4 is rejected under 35 USC §101 as claiming the same invention as that of claim 1 of U.S. Patent No. 6,790,940. Applicants' cancellation of claim 4 renders the rejection moot.

CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to a letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any fees that may be required in connection with this submission, including petition fees and extension of time fees, and to credit any overpayments to Deposit Account No. 23-2415 (Docket No. 31304-760.831).

Respectfully submitted,

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